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PFIZER INC., PHARMACIA CORPORATION,  
AND G.D. SEARLE LLC

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

IN RE BEXTRA AND CELEBREX  
MARKETING, SALES PRACTICES AND  
PRODUCTS LIABILITY LITIGATION

*This document relates to*

ERICK ARONSON, et al.,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,  
and G.D. SEARLE LLC, (FKA G.D. SEARLE &  
CO.),

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-03320-CRB

) **PFIZER INC., PHARMACIA**  
) **CORPORATION, AND G.D.**  
) **SEARLE LLC'S ANSWER TO**  
) **COMPLAINT**

) **JURY DEMAND ENDORSED**  
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as  
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC  
3 ("Searle"), (collectively "Defendants") and file this Answer to Plaintiffs' Complaint  
4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used  
8 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted  
9 generally. Defendants may seek leave to amend this Answer when discovery reveals the  
10 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

11 **II.**

12 **ANSWER**

13 Answering the unnumbered paragraph preceding Paragraph 1 of the Complaint,  
14 Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny  
15 that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain  
16 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United  
17 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
18 accordance with their approval by the FDA. Defendants admit that, during certain periods of  
19 time, Celebrex® was manufactured and packaged for Searle, which developed, tested,  
20 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by  
21 healthcare providers who are by law authorized to prescribe drugs in accordance with their  
22 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used  
23 in accordance with its FDA-approved prescribing information. Defendants state that the  
24 potential effects of Celebrex® were and are adequately described in its FDA-approved  
25 prescribing information, which was at all times adequate and comported with applicable  
26 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused  
27 Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of  
28 the Complaint.

**Response to Allegations Regarding Parties**

1. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and whether Plaintiff is the Representative of Decedent's Estate, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 8. Defendants are without knowledge or information sufficient to form a belief as to the  
3 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
4 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
5 paragraph of the Complaint.

6 9. Defendants are without knowledge or information sufficient to form a belief as to the  
7 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
8 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
9 paragraph of the Complaint.

10 10. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
12 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
13 paragraph of the Complaint.

14 11. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
16 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
17 paragraph of the Complaint.

18 12. Defendants are without knowledge or information sufficient to form a belief as to the  
19 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
20 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
21 paragraph of the Complaint.

22 13. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
24 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this  
25 paragraph of the Complaint.

26 14. Defendants are without knowledge or information sufficient to form a belief as to the  
27 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and  
28 citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 15. Defendants admit that Pfizer is a Delaware corporation with its principal place of  
3 business in New York. Defendants admit that, as the result of a merger in April 2003,  
4 Pharmacia became a subsidiary of Pfizer. Defendants state that the allegations in this paragraph  
5 of the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants  
6 are without knowledge or information sufficient to form a belief as to the truth of such  
7 allegations, and, therefore, deny the same. Defendants admit that, during certain periods of  
8 time, Pfizer marketed and co-promoted Celebrex® in the United States, including Hawaii, to be  
9 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
10 with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of  
11 the Complaint.

12 16. Defendants admit that Searle is a Delaware limited liability company with its principal  
13 place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that,  
14 as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
15 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
16 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
17 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
19 the remaining allegations in this paragraph of the Complaint.

20 17. Defendants admit that Pharmacia is a Delaware corporation with its principal place of  
21 business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as  
22 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.  
23 Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted  
24 Celebrex® in the United States, including Texas and California, to be prescribed by healthcare  
25 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
26 FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

27 18. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
28 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who

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1 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
2 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
3 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
4 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
6 that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle  
7 and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this  
8 paragraph of the Complaint.

9 19. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
10 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
11 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
12 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
13 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
14 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
15 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state  
16 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved  
17 prescribing information. Defendants state that the potential effects of Celebrex® were and are  
18 adequately described in its FDA-approved prescribing information, which was at all times  
19 adequate and comported with applicable standards of care and law. Defendants deny any  
20 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21 20. Defendants state that the allegations in this paragraph of the Complaint regarding  
22 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or  
23 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
24 the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Allegations Regarding Jurisdiction and Venue**

26 21. Defendants are without knowledge or information to form a belief as to the truth of the  
27 allegations in this paragraph of the Complaint regarding Plaintiffs’ citizenship and the amount  
28 in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim

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1 that the parties are diverse and the amount in controversy exceeds \$75,000, exclusive of  
2 interests and costs.

3 22. Defendants are without knowledge or information to form a belief as to the truth of the  
4 allegations in this paragraph of the Complaint regarding the judicial district in which the  
5 asserted claims allegedly arose and, therefore, deny the same. Defendants state that Celebrex®  
6 was and is safe and effective when used in accordance with its FDA-approved prescribing  
7 information. Defendants deny committing a tort in the States of California, Washington,  
8 Delaware, Louisiana, Maryland, Texas, Ohio, Illinois, Pennsylvania, Georgia, and Oregon, and  
9 deny the remaining allegations in this paragraph of the Complaint.

10 23. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
11 and co-promoted Celebrex® in the United States, including Hawaii and California, to be  
12 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance  
13 with their approval by the FDA. Defendants admit that, during certain periods of time,  
14 Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-  
15 promoted and distributed Celebrex® in the United States to be prescribed by healthcare  
16 providers who are by law authorized to prescribe drugs in accordance with their approval by the  
17 FDA. Defendants admit that Pfizer, Pharmacia, and Searle are registered to and do business in  
18 the States of Hawaii and California. Defendants state that the allegations in this paragraph of  
19 the Complaint regarding “predecessors in interest” are vague and ambiguous. Defendants are  
20 without knowledge or information sufficient to form a belief as to the truth of such allegations,  
21 and, therefore, deny the same. Defendants deny committing a tort in the States of California,  
22 Washington, Delaware, Louisiana, Maryland, Texas, Ohio, Illinois, Pennsylvania, Georgia, and  
23 Oregon, and deny the remaining allegations in this paragraph of the Complaint.

24 **Response to Allegations Regarding Interdistrict Assignment**

25 24. Defendants state that this paragraph of the Complaint contains legal contentions to  
26 which no response is required. To the extent that a response is deemed required, Defendants  
27 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.  
28 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial



1 Panel on Multidistrict Litigation on September 6, 2005.

2 **Response to Factual Allegations**

3 25. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used  
5 Celebrex® and, therefore, deny the same. Defendants deny the remaining allegations in this  
6 paragraph of the Complaint.

7 26. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical  
9 condition or whether Plaintiff used Celebrex® and, therefore, deny the same. Defendants state  
10 that Celebrex® was and is safe and effective when used in accordance with its FDA-approved  
11 prescribing information. Defendants state that the potential effects of Celebrex® were and are  
12 adequately described in its FDA-approved prescribing information, which was at all times  
13 adequate and comported with applicable standards of care and law. Defendants deny that  
14 Celebrex® caused Plaintiff injury or damage and deny the remaining allegations in this  
15 paragraph of the Complaint.

16 27. Defendants are without knowledge or information sufficient to form a belief as to the  
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
18 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
19 and is safe and effective when used in accordance with its FDA-approved prescribing  
20 information. Defendants state that the potential effects of Celebrex® were and are adequately  
21 described in its FDA-approved prescribing information, which was at all times adequate and  
22 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
23 deny that Celebrex® caused Plaintiffs or Decedent injury or damage and deny the remaining  
24 allegations in this paragraph of the Complaint.

25 28. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
27 Decedent used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary  
28 case, Celebrex® was expected to reach users and consumers without substantial change from



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1 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 29. Defendants are without knowledge or information sufficient to form a belief as to the  
3 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
4 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
5 and is safe and effective when used in accordance with its FDA-approved prescribing  
6 information. Defendants state that the potential effects of Celebrex® were and are adequately  
7 described in its FDA-approved prescribing information, which was at all times adequate and  
8 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
9 and deny the remaining allegations in this paragraph of the Complaint.

10 30. Defendants state that the allegations in this paragraph of the Complaint regarding  
11 aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no  
12 response is required. Defendants admit that Celebrex® is in a class of drugs that are, at times,  
13 referred to as being non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendants deny the  
14 remaining allegations in this paragraph of the Complaint.

15 31. Defendants state that the allegations in this paragraph of the Complaint are not directed  
16 towards Defendants and, therefore, no response is required. To the extent that a response is  
17 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
18 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
19 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20 32. Defendants state that the allegations in this paragraph of the Complaint are not directed  
21 towards Defendants and, therefore, no response is required. To the extent that a response is  
22 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
23 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information  
24 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

25 33. Defendants state that the allegations in this paragraph of the Complaint are not directed  
26 towards Defendants and, therefore, no response is required. To the extent that a response is  
27 deemed required, Defendants state that Plaintiffs fail to provide the proper context for the  
28 allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information

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1 or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

2 34. Defendants state that the allegations in this paragraph of the Complaint regarding “other  
3 pharmaceutical companies” are not directed towards Defendants and, therefore, no response is  
4 required. To the extent a response is deemed required, Defendants state that, as stated in the  
5 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to  
6 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2  
7 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the  
8 cyclooxygenase-1 (COX-1) isoenzyme.” Plaintiffs fail to provide the proper context for the  
9 remaining allegations in this paragraph and Defendants therefore lack sufficient information or  
10 knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining  
11 allegations in this paragraph of the Complaint.

12 35. Defendants state that the allegations in this paragraph of the Complaint regarding  
13 “predecessors in interest” are vague and ambiguous. Defendants are without knowledge or  
14 information sufficient to form a belief as to the truth of such allegations, and, therefore, deny  
15 the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, “[t]he  
16 mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis,  
17 primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in  
18 humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.” Defendants  
19 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
20 approved prescribing information. Defendants state that the potential effects of Celebrex®  
21 were and are adequately described in its FDA-approved prescribing information, which was at  
22 all times adequate and comported with applicable standards of care and law. Defendants deny  
23 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

24 36. Defendants admit that Searle submitted a New Drug Application (“NDA”) for  
25 Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted  
26 approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of  
27 osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults.  
28 Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to

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1 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis  
2 (“FAP”) as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny  
3 the remaining allegations in this paragraph of the Complaint.

4 37. Defendants admit that Celebrex® was launched in February 1999. Defendants admit  
5 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted  
6 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
7 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit  
8 that, during certain periods of time, Celebrex® was manufactured and packaged for Searle,  
9 which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States  
10 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in  
11 accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe  
12 and effective when used in accordance with its FDA-approved prescribing information.  
13 Defendants state that the potential effects of Celebrex® were and are adequately described in its  
14 FDA-approved prescribing information, which was at all times adequate and comported with  
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the  
16 remaining allegations in this paragraph of the Complaint.

17 38. Defendants state that the referenced article speaks for itself and respectfully refer the  
18 Court to the article for its actual language and text. Any attempt to characterize the article is  
19 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
20 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
21 this paragraph of the Complaint.

22 39. Defendants state that the referenced article speaks for itself and respectfully refer the  
23 Court to the article for its actual language and text. Any attempt to characterize the article is  
24 denied. Defendants state that Celebrex® was and is safe and effective when used in accordance  
25 with its FDA-approved prescribing information. Defendants deny the remaining allegations in  
26 this paragraph of the Complaint.

27 40. Defendants state that the referenced FDA Update speaks for itself and respectfully refer  
28 the Court to the FDA Update for its actual language and text. Any attempt to characterize the

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1 FDA Update is denied. Defendants state that Celebrex® was and is safe and effective when  
2 used in accordance with its FDA-approved prescribing information. Defendants state that the  
3 potential effects of Celebrex® were and are adequately described in its FDA-approved  
4 prescribing information, which was at all times adequate and comported with applicable  
5 standards of care and law. Defendants deny the remaining allegations in this paragraph of the  
6 Complaint.

7 41. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny the allegations in this paragraph of the Complaint.

12 42. Defendants state that Celebrex® was and is safe and effective when used in accordance  
13 with its FDA-approved prescribing information. Defendants state that the potential effects of  
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
15 which was at all times adequate and comported with applicable standards of care and law.  
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
17 the Complaint.

18 43. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA  
19 on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to  
20 characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,  
21 2000, was completed by the FDA. Defendants state that the referenced study speaks for itself  
22 and respectfully refer the Court to the study for its actual language and text. Any attempt to  
23 characterize the study is denied. Defendants deny the remaining allegations in this paragraph of  
24 the Complaint.

25 44. Defendants state that the referenced article speaks for itself and respectfully refer the  
26 Court to the article for its actual language and text. Any attempt to characterize the article is  
27 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28 45. Defendants state that the referenced study speaks for itself and respectfully refer the

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1 Court to the study for its actual language and text. Any attempt to characterize the study is  
2 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
3 paragraph of the Complaint.

4 46. Defendants state that the referenced Medical Officer Review speaks for itself and  
5 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
6 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
7 allegations in this paragraph of the Complaint.

8 47. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee  
9 hearings speak for themselves and respectfully refer the Court to the transcripts for their actual  
10 language and text. Any attempt to characterize the transcripts is denied. Defendants deny any  
11 wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

12 48. Defendants state that the referenced articles speak for themselves and respectfully refer  
13 the Court to the articles for their actual language and text. Any attempt to characterize the  
14 articles is denied. Defendants state that the referenced study speaks for itself and respectfully  
15 refer the Court to the study for its actual language and text. Any attempt to characterize the  
16 study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

17 49. Defendants state that the referenced article speaks for itself and respectfully refer the  
18 Court to the article for its actual language and text. Any attempt to characterize the article is  
19 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
20 paragraph of the Complaint.

21 50. Defendants state that the referenced articles speak for themselves and respectfully refer  
22 the Court to the articles for their actual language and text. Any attempt to characterize the  
23 articles is denied. Defendants deny the remaining allegations in this paragraph of the  
24 Complaint.

25 51. Defendants state that the referenced article speaks for itself and respectfully refer the  
26 Court to the article for its actual language and text. Any attempt to characterize the article is  
27 denied. Defendants state that the referenced study speaks for itself and respectfully refer the  
28 Court to the study for its actual language and text. Any attempt to characterize the study is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 52. Defendants state that the referenced Medical Officer Review speaks for itself and  
3 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
4 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
5 allegations in this paragraph of the Complaint.

6 53. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
7 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
8 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 54. Defendants state that the referenced article speaks for itself and respectfully refer the  
11 Court to the article for its actual language and text. Any attempt to characterize the article is  
12 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this  
13 paragraph of the Complaint.

14 55. Defendants state that the referenced study speaks for itself and respectfully refer the  
15 Court to the study for its actual language and text. Any attempt to characterize the study is  
16 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Public  
17 Citizen” in this paragraph of the Complaint. Defendants therefore lack sufficient information or  
18 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.  
19 Defendants deny the remaining allegations in this paragraph of the Complaint.

20 56. Defendants admit that there was a clinical trial called APC. Defendants state that the  
21 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
22 language and text. Any attempt to characterize the article is denied. Defendants deny the  
23 remaining allegations in this paragraph of the Complaint.

24 57. Defendants state that the referenced article speaks for itself and respectfully refer the  
25 Court to the article for its actual language and text. Any attempt to characterize the article is  
26 denied. Plaintiffs fail to provide the proper context for the allegations concerning “Data Safety  
27 Monitoring Board” in this paragraph of the Complaint. Defendants therefore lack sufficient  
28 information or knowledge to form a belief as to the truth of such allegations and, therefore,

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1 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 58. Defendants state that the referenced article speaks for itself and respectfully refer the  
3 Court to the article for its actual language and text. Any attempt to characterize the article is  
4 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

5 59. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself  
6 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language  
7 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.  
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 60. Defendants state that the referenced Medical Officer Review speaks for itself and  
10 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
11 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
12 allegations in this paragraph of the Complaint.

13 61. Defendants admit that there was a clinical trial called PreSAP. Plaintiffs fail to provide  
14 the proper context for the allegations concerning “other Celebrex trials” contained in this  
15 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to  
16 form a belief as to the truth of such allegations and, therefore, deny the same. As for the  
17 allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state  
18 that the referenced study speaks for itself and respectfully refer the Court to the study for its  
19 actual language and text. Any attempt to characterize the study is denied. Defendants deny the  
20 remaining allegations in this paragraph of the Complaint.

21 62. Defendants state that the referenced article speaks for itself and respectfully refer the  
22 Court to the article for its actual language and text. Any attempt to characterize the article is  
23 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

24 63. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the  
25 Complaint regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants  
26 therefore lack sufficient information or knowledge to form a belief as to the truth of such  
27 allegations and, therefore, deny the same. Defendants state that the referenced studies speak for  
28 themselves and respectfully refer the Court to the studies for their actual language and text.



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1 Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in  
2 this paragraph of the Complaint.

3 64. Defendants state that the referenced Medical Officer Review speaks for itself and  
4 respectfully refer the Court to the Medical Officer Review for its actual language and text. Any  
5 attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining  
6 allegations in this paragraph of the Complaint.

7 65. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint  
8 are not directed toward Defendants, and therefore no response is required. To the extent that a  
9 response is deemed required, Plaintiffs fail to provide the proper context for the allegations in  
10 this paragraph of the Complaint regarding Vioxx® in this paragraph of the Complaint.  
11 Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of  
12 such allegations and, therefore, deny the same. Defendants state that the referenced study  
13 speaks for itself and respectfully refer the Court to the study for its actual language and text.  
14 Any attempt to characterize the study is denied. Defendants deny the remaining allegations in  
15 this paragraph of the Complaint.

16 66. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the  
17 Complaint are not directed toward Defendants, and therefore no response is required. To the  
18 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the  
19 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph  
20 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a  
21 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the  
22 referenced study speaks for itself and respectfully refer the Court to the study for its actual  
23 language and text. Any attempt to characterize the study is denied. Defendants deny the  
24 remaining allegations in this paragraph of the Complaint.

25 67. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the  
26 Complaint are not directed toward Defendants, and therefore no response is required. To the  
27 extent that a response is deemed required, Plaintiffs fail to provide the proper context for the  
28 allegations in this paragraph of the Complaint regarding Merck and Vioxx® in this paragraph

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1 of the Complaint. Defendants therefore lack sufficient information or knowledge to form a  
2 belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the  
3 referenced study speaks for itself and respectfully refer the Court to the study for its actual  
4 language and text. Any attempt to characterize the study is denied. Defendants state that the  
5 referenced article speaks for itself and respectfully refer the Court to the article for its actual  
6 language and text. Any attempt to characterize the article is denied. Defendants deny the  
7 remaining allegations in this paragraph of the Complaint.

8 68. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants deny the allegations in this  
10 paragraph of the Complaint.

11 69. Defendants state that the referenced article speaks for itself and respectfully refer the  
12 Court to the article for its actual language and text. Any attempt to characterize the article is  
13 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

14 70. Defendants state that allegations in this paragraph of the Complaint are not directed  
15 toward Defendants, and therefore no response is required. To the extent that a response is  
16 deemed required, Defendants state that the referenced article speaks for itself and respectfully  
17 refer the Court to the article for its actual language and text. Any attempt to characterize the  
18 article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 71. Defendants deny the allegations in this paragraph of the Complaint.

20 72. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
25 remaining allegations contained in this paragraph of the Complaint.

26 73. Defendants deny any wrongful conduct and deny the allegations contained in this  
27 paragraph of the Complaint.

28 74. Defendants deny any wrongful conduct and deny the allegations contained in this

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1 paragraph of the Complaint.

2 75. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which was at all times adequate and comported with applicable standards of care and law.  
6 Defendants deny any wrongful conduct and deny the remaining allegations contained in this  
7 paragraph of the Complaint.

8 76. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
10 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
11 and is safe and effective when used in accordance with its FDA-approved prescribing  
12 information. Defendants state that the potential effects of Celebrex® were and are adequately  
13 described in its FDA-approved prescribing information, which was at all times adequate and  
14 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
15 deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this  
16 paragraph of the Complaint.

17 77. Defendants admit that the FDA Division of Drug Marketing, Advertising, and  
18 Communications (“DDMAC”) sent letters to Searle dated October 6, 1999, April 6, 2000, and  
19 November 14, 2000. Defendants state that the referenced letters speak for themselves and  
20 respectfully refer the Court to the letters for their actual language and text. Any attempt to  
21 characterize the letters is denied. Defendants deny the remaining allegations in this paragraph  
22 of the Complaint.

23 78. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001.  
24 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to  
25 the letter for its actual language and text. Any attempt to characterize the letter is denied.  
26 Defendants deny the remaining allegations in this paragraph of the Complaint.

27 79. Defendants state that the referenced article speaks for itself and respectfully refer the  
28 Court to the article for its actual language and text. Any attempt to characterize the article is

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1 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

2 80. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005.  
3 Defendants state that the referenced letter speaks for itself and respectfully refer the Court to  
4 the letter for its actual language and text. Any attempt to characterize the letter is denied.  
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 81. Defendants state that Celebrex® was and is safe and effective when used in accordance  
7 with its FDA-approved prescribing information. Defendants state that the potential effects of  
8 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
9 which was at all times adequate and comported with applicable standards of care and law.  
10 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
11 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
12 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
13 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
14 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
15 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
16 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
17 allegations in this paragraph of the Complaint.

18 82. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
23 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
25 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
26 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
27 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
28 drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a

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1 prescription medication which is approved by the FDA for the following indications: (1) for  
2 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of  
3 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
4 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
5 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
6 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
7 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
8 and older. Defendants deny any wrongful conduct and deny the remaining allegations in this  
9 paragraph of the Complaint.

10 83. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which at all times was adequate and comported with applicable standards of care and law.  
14 Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and  
15 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of  
16 such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny  
17 that Celebrex® is defective, and deny the allegations in this paragraph of the Complaint.

18 84. Defendants state that Celebrex® was and is safe and effective when used in accordance  
19 with its FDA-approved prescribing information. Defendants state that the potential effects of  
20 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
21 which was at all times adequate and comported with applicable standards of care and law.  
22 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
23 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
24 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
25 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
26 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
27 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
28 drugs in accordance with their approval by the FDA. Defendants deny the remaining

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1 allegations in this paragraph of the Complaint.

2 85. Defendants state that Celebrex® was and is safe and effective when used in accordance  
3 with its FDA-approved prescribing information. Defendants state that the potential effects of  
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
5 which at all times was adequate and comported with applicable standards of care and law.  
6 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-  
7 promoted Celebrex® in the United States to be prescribed by healthcare providers who are by  
8 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants  
9 admit that, during certain periods of time, Celebrex® was manufactured and packaged for  
10 Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the  
11 United States to be prescribed by healthcare providers who are by law authorized to prescribe  
12 drugs in accordance with their approval by the FDA. Defendants deny the remaining  
13 allegations in this paragraph of the Complaint.

14 86. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
19 the Complaint.

20 87. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
25 the Complaint.

26 88. Defendants deny the allegations in this paragraph of the Complaint.

27 89. Defendants state that Celebrex® was and is safe and effective when used in accordance  
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
4 the Complaint.

5 90. Defendants state that Celebrex® was and is safe and effective when used in accordance  
6 with its FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 91. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
13 Decedent used Celebrex® and, therefore, deny the same. Defendants deny any wrongful  
14 conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the  
15 remaining allegations in this paragraph of the Complaint.

16 92. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
21 remaining allegations in this paragraph of the Complaint.

22 93. Defendants state that Celebrex® was and is safe and effective when used in accordance  
23 with its FDA-approved prescribing information. Defendants state that the potential effects of  
24 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
25 which was at all times adequate and comported with applicable standards of care and law.  
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
27 the Complaint.

28 94. Defendants state that Celebrex® was and is safe and effective when used in accordance



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1 with its FDA-approved prescribing information. Defendants state that the potential effects of  
2 Celebrex® are and were adequately described in its FDA-approved prescribing information,  
3 which was at all times adequate and comported with applicable standards of care and law.  
4 Defendants state that the referenced study speaks for itself and respectfully refer the Court to  
5 the study for its actual language and text. Any attempt to characterize the study is denied.  
6 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
7 the Complaint.

8 95. Defendants deny any wrongful conduct and deny the remaining allegations in this  
9 paragraph of the Complaint.

10 96. Defendants are without knowledge or information sufficient to form a belief as to the  
11 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
12 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
13 and is safe and effective when used in accordance with its FDA-approved prescribing  
14 information. Defendants state that the potential effects of Celebrex® are and were adequately  
15 described in its FDA-approved prescribing information, which was at all times adequate and  
16 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
17 and deny the remaining allegations in this paragraph of the Complaint.

18 **Response to First Cause of Action: Negligence**

19 97. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
20 Complaint as if fully set forth herein.

21 98. Defendants state that this paragraph of the Complaint contains legal contentions to  
22 which no response is required. To the extent that a response is deemed required, Defendants  
23 admit that they had duties as are imposed by law but deny having breached such duties.  
24 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
25 FDA-approved prescribing information. Defendants state that the potential effects of  
26 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
27 which was at all times adequate and comported with applicable standards of care and law.  
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 99. Defendants state that this paragraph of the Complaint contains legal contentions to  
3 which no response is required. To the extent that a response is deemed required, Defendants  
4 admit that they had duties as are imposed by law but deny having breached such duties.  
5 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
6 FDA-approved prescribing information. Defendants state that the potential effects of  
7 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
8 which was at all times adequate and comported with applicable standards of care and law.  
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
10 the Complaint.

11 100. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
13 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
14 and is safe and effective when used in accordance with its FDA-approved prescribing  
15 information. Defendants state that the potential effects of Celebrex® were and are adequately  
16 described in its FDA-approved prescribing information, which was at all times adequate and  
17 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
18 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

19 101. Defendants are without knowledge or information sufficient to form a belief as to the  
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
21 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
22 and is safe and effective when used in accordance with its FDA-approved prescribing  
23 information. Defendants state that the potential effects of Celebrex® were and are adequately  
24 described in its FDA-approved prescribing information, which was at all times adequate and  
25 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
26 and deny the remaining allegations in this paragraph of the Complaint.

27 102. Defendants are without knowledge or information sufficient to form a belief as to the  
28 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or

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1 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
2 and is safe and effective when used in accordance with its FDA-approved prescribing  
3 information. Defendants state that the potential effects of Celebrex® were and are adequately  
4 described in its FDA-approved prescribing information, which was at all times adequate and  
5 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
6 and deny the remaining allegations in this paragraph of the Complaint.

7 103. Defendants state that Celebrex® was and is safe and effective when used in accordance  
8 with its FDA-approved prescribing information. Defendants state that the potential effects of  
9 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
10 which was at all times adequate and comported with applicable standards of care and law.  
11 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
12 the Complaint.

13 104. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
15 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
20 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining  
21 allegations in this paragraph of the Complaint.

22 105. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
23 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
24 Complaint.

25 106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
26 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
27 Complaint.

28

**Response to Second Cause of Action: Strict Liability**

107. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

109. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

110. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the remaining allegations in this paragraph of the Complaint.

111. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
2 which was at all times adequate and comported with applicable standards of care and law.  
3 Defendants deny that Celebrex® is defective or unreasonably dangerous and deny the  
4 remaining allegations in this paragraph of the Complaint, including all subparts.

5 112. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
7 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
8 and is safe and effective when used in accordance with its FDA-approved prescribing  
9 information. Defendants state that the potential effects of Celebrex® were and are adequately  
10 described in its FDA-approved prescribing information, which was at all times adequate and  
11 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
12 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or  
13 damage, and deny the remaining allegations in this paragraph of the Complaint.

14 113. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the  
19 remaining allegations in this paragraph of the Complaint.

20 114. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
22 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
23 and is safe and effective when used in accordance with its FDA-approved prescribing  
24 information. Defendants state that the potential effects of Celebrex® were and are adequately  
25 described in its FDA-approved prescribing information, which was at all times adequate and  
26 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
27 deny that Celebrex® is defective, deny that Celebrex® caused Plaintiffs or Decedent injury or  
28 damage, and deny the remaining allegations in this paragraph of the Complaint.

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1 115. Defendants state that Celebrex® was and is safe and effective when used in accordance  
2 with its FDA-approved prescribing information. Defendants state that the potential effects of  
3 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
4 which was at all times adequate and comported with applicable standards of care and law.  
5 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
6 the Complaint.

7 116. Defendants are without knowledge or information sufficient to form a belief as to the  
8 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
9 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
10 and is safe and effective when used in accordance with its FDA-approved prescribing  
11 information. Defendants state that the potential effects of Celebrex® were and are adequately  
12 described in its FDA-approved prescribing information, which was at all times adequate and  
13 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
14 deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining  
15 allegations in this paragraph of the Complaint.

16 117. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 118. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
24 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants deny any wrongful conduct

1 and deny the remaining allegations in this paragraph of the Complaint.

2 119. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
3 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
4 Complaint.

5 120. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
6 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
7 Complaint.

8 121. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
9 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
10 Complaint.

11 **Response to Third Cause of Action: Breach of Express Warranty**

12 122. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
13 Complaint as if fully set forth herein.

14 123. Defendants are without knowledge or information sufficient to form a belief as to the  
15 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
16 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
17 and is safe and effective when used in accordance with its FDA-approved prescribing  
18 information. Defendants state that the potential effects of Celebrex® were and are adequately  
19 described in its FDA-approved prescribing information, which was at all times adequate and  
20 comported with applicable standards of care and law. Defendants admit that they provided  
21 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining  
22 allegations in this paragraph of the Complaint.

23 124. Defendants are without knowledge or information sufficient to form a belief as to the  
24 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
25 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
26 and is safe and effective when used in accordance with its FDA-approved prescribing  
27 information. Defendants state that the potential effects of Celebrex® were and are adequately  
28 described in its FDA-approved prescribing information, which was at all times adequate and

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1 comported with applicable standards of care and law. Defendants admit that they provided  
2 FDA-approved prescribing information regarding Celebrex®. Defendants deny any wrongful  
3 conduct and deny the remaining allegations in this paragraph of the Complaint, including all  
4 subparts.

5 125. Defendants admit that they provided FDA-approved prescribing information regarding  
6 Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 126. Defendants state that Celebrex® was and is safe and effective when used in accordance  
9 with its FDA-approved prescribing information. Defendants state that the potential effects of  
10 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
11 which was at all times adequate and comported with applicable standards of care and law.  
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
13 the Complaint.

14 127. Defendants state that Celebrex® was and is safe and effective when used in accordance  
15 with its FDA-approved prescribing information. Defendants state that the potential effects of  
16 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
17 which was at all times adequate and comported with applicable standards of care and law.  
18 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
19 the Complaint.

20 128. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
22 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that the potential  
23 effects of Celebrex® were and are adequately described in its FDA-approved prescribing  
24 information, which was at all times adequate and comported with applicable standards of care  
25 and law. Defendants admit that they provided FDA-approved prescribing information  
26 regarding Celebrex®. Defendants deny the remaining allegations in this paragraph of the  
27 Complaint.

28 129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or

1 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
2 Complaint.

3 130. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
4 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
5 Complaint.

6 131. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
7 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
8 Complaint.

9 **Response to Fourth Cause of Action: Breach of Implied Warranty**

10 132. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
11 Complaint as if fully set forth herein.

12 133. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
13 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
14 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
15 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
16 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
17 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
18 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
19 the remaining allegations in this paragraph of the Complaint.

20 134. Defendants state that Celebrex® was and is safe and effective when used in accordance  
21 with its FDA-approved prescribing information. Defendants state that the potential effects of  
22 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
23 which was at all times adequate and comported with applicable standards of care and law.  
24 Defendants admit that they provided FDA-approved prescribing information regarding  
25 Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

26 135. Defendants state that Celebrex® was and is safe and effective when used in accordance  
27 with its FDA-approved prescribing information. Defendants state that the potential effects of  
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.  
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 136. Defendants state that this paragraph of the Complaint contains legal contentions to  
4 which no response is required. To the extent that a response is deemed required, Defendants  
5 state that Celebrex® was and is safe and effective when used in accordance with its FDA-  
6 approved prescribing information. Defendants state that the potential effects of Celebrex®  
7 were and are adequately described in its FDA-approved prescribing information, which was at  
8 all times adequate and comported with applicable standards of care and law. Defendants deny  
9 any wrongful conduct, deny that they breached any warranty, and deny the remaining  
10 allegations in this paragraph of the Complaint.

11 137. Defendants are without knowledge or information sufficient to form a belief as to the  
12 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
13 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a  
14 prescription medication which is approved by the FDA for the following indications: (1) for  
15 relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of  
16 rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the  
17 treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps  
18 in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic  
19 surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for  
20 relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age  
21 and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 138. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
24 Decedent used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants admit that they provided

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1 FDA-approved prescribing information regarding Celebrex®. Defendants deny the remaining  
2 allegations in this paragraph of the Complaint.

3 139. Defendants are without knowledge or information sufficient to form a belief as to the  
4 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
5 Decedent used Celebrex® and, therefore, deny the same. Defendants state that, in the ordinary  
6 case, Celebrex® was expected to reach users and consumers without substantial change from  
7 the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

8 140. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
10 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
11 and is safe and effective when used in accordance with its FDA-approved prescribing  
12 information. Defendants state that the potential effects of Celebrex® were and are adequately  
13 described in its FDA-approved prescribing information, which was at all times adequate and  
14 comported with applicable standards of care and law. Defendants deny any wrongful conduct,  
15 deny that they breached any warranty, and deny the remaining allegations in this paragraph of  
16 the Complaint.

17 141. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
18 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
19 Complaint.

20 142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
21 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
22 Complaint.

23 143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
24 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
25 Complaint.

26 **Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment**

27 144. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
28 Complaint as if fully set forth herein.

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1 145. Defendants state that this paragraph of the Complaint contains legal contentions to  
2 which no response is required. To the extent that a response is deemed required, Defendants  
3 admit that they had duties as are imposed by law but deny having breached such duties.  
4 Defendants state that Celebrex® was and is safe and effective when used in accordance with its  
5 FDA-approved prescribing information. Defendants state that the potential effects of  
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
7 which was at all times adequate and comported with applicable standards of care and law.  
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
9 the Complaint.

10 146. Defendants state that Celebrex® was and is safe and effective when used in accordance  
11 with its FDA-approved prescribing information. Defendants state that the potential effects of  
12 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
13 which was at all times adequate and comported with applicable standards of care and law.  
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
15 the Complaint, including all subparts.

16 147. Defendants state that Celebrex® was and is safe and effective when used in accordance  
17 with its FDA-approved prescribing information. Defendants state that the potential effects of  
18 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
19 which was at all times adequate and comported with applicable standards of care and law.  
20 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
21 the Complaint.

22 148. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
24 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
25 and is safe and effective when used in accordance with its FDA-approved prescribing  
26 information. Defendants state that the potential effects of Celebrex® were and are adequately  
27 described in its FDA-approved prescribing information, which was at all times adequate and  
28 comported with applicable standards of care and law. Defendants deny any wrongful conduct,

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1 deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining  
2 allegations in this paragraph of the Complaint, including all subparts.

3 149. Defendants state that Celebrex® was and is safe and effective when used in accordance  
4 with its FDA-approved prescribing information. Defendants state that the potential effects of  
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,  
6 which was at all times adequate and comported with applicable standards of care and law.  
7 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of  
8 the Complaint.

9 150. Defendants are without knowledge or information sufficient to form a belief as to the  
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
11 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
12 and is safe and effective when used in accordance with its FDA-approved prescribing  
13 information. Defendants state that the potential effects of Celebrex® were and are adequately  
14 described in its FDA-approved prescribing information, which was at all times adequate and  
15 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
16 and deny the remaining allegations in this paragraph of the Complaint.

17 151. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
19 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
20 and is safe and effective when used in accordance with its FDA-approved prescribing  
21 information. Defendants state that the potential effects of Celebrex® were and are adequately  
22 described in its FDA-approved prescribing information, which was at all times adequate and  
23 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
24 and deny the remaining allegations in this paragraph of the Complaint.

25 152. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
27 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
28 and is safe and effective when used in accordance with its FDA-approved prescribing

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1 information. Defendants state that the potential effects of Celebrex® were and are adequately  
2 described in its FDA-approved prescribing information, which was at all times adequate and  
3 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
4 and deny the remaining allegations in this paragraph of the Complaint.

5 153. Defendants are without knowledge or information sufficient to form a belief as to the  
6 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
7 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
8 and is safe and effective when used in accordance with its FDA-approved prescribing  
9 information. Defendants state that the potential effects of Celebrex® were and are adequately  
10 described in its FDA-approved prescribing information, which was at all times adequate and  
11 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
12 and deny the remaining allegations in this paragraph of the Complaint.

13 154. Defendants are without knowledge or information sufficient to form a belief as to the  
14 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
15 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
16 and is safe and effective when used in accordance with its FDA-approved prescribing  
17 information. Defendants state that the potential effects of Celebrex® were and are adequately  
18 described in its FDA-approved prescribing information, which was at all times adequate and  
19 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
20 and deny the remaining allegations in this paragraph of the Complaint.

21 155. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
23 Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was  
24 and is safe and effective when used in accordance with its FDA-approved prescribing  
25 information. Defendants state that the potential effects of Celebrex® were and are adequately  
26 described in its FDA-approved prescribing information, which was at all times adequate and  
27 comported with applicable standards of care and law. Defendants deny any wrongful conduct  
28 and deny the remaining allegations in this paragraph of the Complaint.



1 156. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
2 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
3 Complaint.

4 157. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
6 Complaint.

7 158. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
9 Complaint.

10 **Response to Sixth Cause of Action: Unjust Enrichment**

11 159. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
12 Complaint as if fully set forth herein.

13 160. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed  
14 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who  
15 are by law authorized to prescribe drugs in accordance with their approval by the FDA.  
16 Defendants admit that, during certain periods of time, Celebrex® was manufactured and  
17 packaged for Searle, which developed, tested, marketed, co-promoted and distributed  
18 Celebrex® in the United States to be prescribed by healthcare providers who are by law  
19 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny  
20 the remaining allegations in this paragraph of the Complaint.

21 161. Defendants are without knowledge or information sufficient to form a belief as to the  
22 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
23 Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining  
24 allegations in this paragraph of the Complaint.

25 162. Defendants are without knowledge or information sufficient to form a belief as to the  
26 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
27 Decedent used Celebrex® and, therefore, deny the same. Defendants deny the remaining  
28 allegations in this paragraph of the Complaint.

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163. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

164. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or Decedent used Celebrex® and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

**Response to Seventh Cause of Action:**

**State Consumer Fraud and Deceptive Trade Practices Act**

166. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

167. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants deny the remaining allegations in this paragraph of the Complaint.

168. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding whether Plaintiffs or Decedent used Celebrex® and, therefore,  
2 deny the same. Defendants state that Celebrex® was and is safe and effective when used in  
3 accordance with its FDA-approved prescribing information. Defendants state that the potential  
4 effects of Celebrex® were and are adequately described in its FDA-approved prescribing  
5 information, which was at all times adequate and comported with applicable standards of care  
6 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
7 paragraph of the Complaint.

8 169. Defendants are without knowledge or information sufficient to form a belief as to the  
9 truth of the allegations regarding whether Plaintiffs or Decedent used Celebrex® and, therefore,  
10 deny the same. Defendants state that Celebrex® was and is safe and effective when used in  
11 accordance with its FDA-approved prescribing information. Defendants state that the potential  
12 effects of Celebrex® were and are adequately described in its FDA-approved prescribing  
13 information, which was at all times adequate and comported with applicable standards of care  
14 and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
15 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
16 Complaint.

17 170. Defendants are without knowledge or information sufficient to form a belief as to the  
18 truth of the allegations regarding whether Plaintiffs or Decedent used Celebrex® and, therefore,  
19 deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

20 171. Defendants are without knowledge or information sufficient to form a belief as to the  
21 truth of the allegations regarding whether Plaintiffs or Decedent used Celebrex® and, therefore,  
22 deny the same. Defendants state that Celebrex® was and is safe and effective when used in  
23 accordance with its FDA-approved prescribing information. Defendants state that the potential  
24 effects of Celebrex® were and are adequately described in its FDA-approved prescribing  
25 information, which was at all times adequate and comported with applicable standards of care  
26 and law. Defendants deny any wrongful conduct and deny the remaining allegations in this  
27 paragraph of the Complaint.

28 172. Defendants state that this paragraph of the Complaint contains legal contentions to

1 which no response is required. To the extent that a response is deemed required, Defendants  
2 deny any wrongful conduct and deny the remaining allegations in this paragraph of the  
3 Complaint.

4 173. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
5 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
6 Complaint.

7 174. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
8 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
9 Complaint.

10 175. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
11 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
12 Complaint.

13 176. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
14 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
15 Complaint.

16 177. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
17 Decedent injury or damage, and deny the remaining allegations in this paragraph of the  
18 Complaint.

19 **Response to Eighth Cause of Action: State Suppliers Liability Statute**

20 178. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'  
21 Complaint as if fully set forth herein.

22 179. Defendants are without knowledge or information sufficient to form a belief as to the  
23 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs or  
24 Decedent used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful  
25 conduct, deny that Celebrex® caused Plaintiffs or Decedent injury or damage, and deny the  
26 remaining allegations in this paragraph of the Complaint.

27 180. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
28 Decedent injury or damage, and deny the remaining allegations in this paragraph of the

1 Complaint.

2 **Response to Prayer For Relief**

3 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs or  
4 Decedent injury or damage, and deny the remaining allegations in paragraph of the Complaint  
5 headed “Prayer for Relief,” including all subparts.

6 **III.**

7 **GENERAL DENIAL**

8 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs’  
9 Complaint that have not been previously admitted, denied, or explained.

10 **IV.**

11 **AFFIRMATIVE DEFENSES**

12 Defendants reserve the right to rely upon any of the following or additional defenses to  
13 claims asserted by Plaintiffs to the extent that such defenses are supported by information  
14 developed through discovery or evidence at trial. Defendants affirmatively show that:

15 **First Defense**

16 1. The Complaint fails to state a claim upon which relief can be granted.

17 **Second Defense**

18 2. Celebrex® is a prescription medical product. The federal government has preempted  
19 the field of law applicable to the labeling and warning of prescription medical products.  
20 Defendants’ labeling and warning of Celebrex® was at all times in compliance with applicable  
21 federal law. Plaintiffs’ causes of action against Defendants, therefore, fail to state a claim upon  
22 which relief can be granted; such claims, if allowed, would conflict with applicable federal law  
23 and violate the Supremacy Clause of the United States Constitution.

24 **Third Defense**

25 3. At all relevant times, Defendants provided proper warnings, information and  
26 instructions for the drug in accordance with generally recognized and prevailing standards in  
27 existence at the time.

**Fourth Defense**

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

**Fifth Defense**

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

**Sixth Defense**

6. Plaintiffs' action is barred by the statute of repose.

**Seventh Defense**

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs and Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

**Eighth Defense**

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

**Ninth Defense**

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

**Tenth Defense**

10. Any injuries or expenses incurred by Plaintiffs or Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

**Eleventh Defense**

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs or Decedent.

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**Twelfth Defense**

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’ and Decedent’s treating and prescribing physicians.

**Thirteenth Defense**

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

**Fourteenth Defense**

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

**Fifteenth Defense**

15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs and Decedent was prepared in accordance with the applicable standard of care.

**Sixteenth Defense**

16. Plaintiffs’ and Decedent’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

**Seventeenth Defense**

17. Plaintiffs’ alleged damages were not caused by any failure to warn on the part of Defendants.



**Eighteenth Defense**

18. Plaintiffs' and Decedent's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

**Nineteenth Defense**

19. Plaintiffs and Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

**Twentieth Defense**

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

**Twenty-first Defense**

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**Twenty-second Defense**

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

**Twenty-third Defense**

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

**Twenty-fourth Defense**

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

**Twenty-fifth Defense**

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate

1 “direction or warnings” as to the use of the subject pharmaceutical product within the meaning  
2 of Comment j to Section 402A of the Restatement (Second) of Torts.

3 **Twenty-sixth Defense**

4 26. Plaintiffs’ claims are barred or limited to a product liability failure to warn claim  
5 because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of  
6 Restatement (Second) of Torts § 402A, Comment k.

7 **Twenty-seventh Defense**

8 27. Plaintiffs’ claims are barred in whole or in part because the subject pharmaceutical  
9 product at issue “provides net benefits for a class of patients” within the meaning of Comment f  
10 to § 6 of the Restatement (Third) of Torts: Products Liability.

11 **Twenty-eighth Defense**

12 28. Plaintiffs’ claims are barred under § 4, et seq., of the Restatement (Third) of Torts:  
13 Products Liability.

14 **Twenty-ninth Defense**

15 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead  
16 facts sufficient under the law to justify an award of punitive damages.

17 **Thirtieth Defense**

18 30. Defendants affirmatively aver that the imposition of punitive damages in this case  
19 would violate Defendants’ rights to procedural due process under the Fourteenth Amendment of  
20 the United States Constitution and the Constitutions of the States of California, Washington,  
21 Delaware, Louisiana, Maryland, Texas, Ohio, Illinois, Pennsylvania, Georgia, and Oregon, and  
22 would additionally violate Defendants’ rights to substantive due process under the Fourteenth  
23 Amendment of the United States Constitution.

24 **Thirty-first Defense**

25 31. Plaintiffs’ claims for punitive damages are barred, in whole or in part, by the Fifth and  
26 Fourteenth Amendments to the United States Constitution.

27 **Thirty-second Defense**

28 32. The imposition of punitive damages in this case would violate the First Amendment to

the United States Constitution.

**Thirty-third Defense**

33. Plaintiffs' punitive damage claims are preempted by federal law.

**Thirty-fourth Defense**

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

**Thirty-fifth Defense**

35. Plaintiffs and Decedent failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

**Thirty-sixth Defense**

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

**Thirty-seventh Defense**

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**Thirty-eighth Defense**

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of California, Washington, Delaware, Louisiana, Maryland, Texas, Ohio, Illinois, Pennsylvania, Georgia, and Oregon. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is

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1 unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks  
2 constitutionally sufficient standards to guide and restrain the jury's discretion in determining  
3 whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that  
4 it failed to provide adequate advance notice as to what conduct will result in punitive damages;  
5 (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied  
6 with applicable law, or conduct that was not directed, or did not proximately cause harm, to  
7 Plaintiffs and Decedent; (4) permits recovery of punitive damages in an amount that is not both  
8 reasonable and proportionate to the amount of harm, if any, to Plaintiffs and Decedent and to  
9 the amount of compensatory damages, if any; (5) permits jury consideration of net worth or  
10 other financial information relating to Defendants; (6) lacks constitutionally sufficient standards  
11 to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks  
12 constitutionally sufficient standards for appellate review of punitive damages awards; and (8)  
13 otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific*  
14 *Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance*  
15 *Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559  
16 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

### **Thirty-ninth Defense**

17  
18 39. The methods, standards, and techniques utilized with respect to the manufacture, design,  
19 and marketing of Celebrex®, if any, used in this case, included adequate warnings and  
20 instructions with respect to the product's use in the package insert and other literature, and  
21 conformed to the generally recognized, reasonably available, and reliable state of the  
22 knowledge at the time the product was marketed.

### **Fortieth Defense**

23  
24 40. The claims asserted in the Complaint are barred because Celebrex® was designed,  
25 tested, manufactured and labeled in accordance with the state-of-the-art industry standards  
26 existing at the time of the sale.

### **Forty-first Defense**

27  
28 41. If Plaintiffs and Decedent have sustained injuries or losses as alleged in the Complaint,

1 upon information and belief, such injuries and losses were caused by the actions of persons not  
2 having real or apparent authority to take said actions on behalf of Defendants and over whom  
3 Defendants had no control and for whom Defendants may not be held accountable.

4 **Forty-second Defense**

5 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
6 was not unreasonably dangerous or defective, was suitable for the purpose for which it was  
7 intended, and was distributed with adequate and sufficient warnings.

8 **Forty-third Defense**

9 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,  
10 waiver, and/or estoppel.

11 **Forty-fourth Defense**

12 44. Plaintiffs' claims are barred because Plaintiffs' and Decedent's injuries, if any, were the  
13 result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions,  
14 diseases or illnesses, subsequent medical conditions or natural courses of conditions of  
15 Plaintiffs and Decedent, and were independent of or far removed from Defendants' conduct.

16 **Forty-fifth Defense**

17 45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®  
18 did not proximately cause injuries or damages to Plaintiffs or Decedent.

19 **Forty-sixth Defense**

20 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs  
21 did not incur any ascertainable loss as a result of Defendants' conduct.

22 **Forty-seventh Defense**

23 47. The claims asserted in the Complaint are barred, in whole or in part, because the  
24 manufacturing, labeling, packaging, and any advertising of the product complied with the  
25 applicable codes, standards and regulations established, adopted, promulgated or approved by  
26 any applicable regulatory body, including but not limited to the United States, any state, and  
27 any agency thereof.

28

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**Forty-eighth Defense**

48. The claims must be dismissed because Plaintiffs and Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

**Forty-ninth Defense**

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

**Fiftieth Defense**

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

**Fifty-first Defense**

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs and Decedent.

**Fifty-second Defense**

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

**Fifty-third Defense**

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the

1 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the  
2 United States.

3 **Fifty-fourth Defense**

4 54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity  
5 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

6 **Fifty-fifth Defense**

7 55. Defendants state on information and belief that the Complaint and each purported cause  
8 of action contained therein is barred by the statutes of limitations contained in California Code  
9 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation  
10 as may apply.

11 **Fifty-sixth Defense**

12 56. Defendants state on information and belief that any injuries, losses, or damages suffered  
13 by Plaintiffs and Decedent were proximately caused, in whole or in part, by the negligence or  
14 other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs'  
15 recovery against Defendants, if any, should be reduced pursuant to California Civil Code §  
16 1431.2.

17 **Fifty-seventh Defense**

18 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of  
19 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil  
20 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive  
21 damages is also barred under California Civil Code § 3294(b).

22 **Fifty-eighth Defense**

23 58. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code  
24 § 82.007.

25 **Fifty-ninth Defense**

26 59. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code  
27 § 82.003.

28

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**Sixtieth Defense**

60. Plaintiffs' causes of action are barred by Texas Civil Practice & Remedies Code § 16.012.

**Sixty-first Defense**

61. This action is subject to the proportionate responsibility provisions of Chapter 33 of the Texas Civil Practice and Remedies Code, including (without limitation) the requirement of § 33.003 thereof that the trier of fact determine the relative responsibility of each claimant, Defendants, and responsible third-party that may be joined in the suit.

**Sixty-second Defense**

62. If Plaintiffs settle with any other person or entity, then Defendants reserve the right to make a written election of credit for settlements under § 33.014 of the Texas Civil Practice and Remedies Code.

**Sixty-third Defense**

63. Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

**Sixty-fourth Defense**

64. Plaintiffs' claims are barred in whole or in part because any alleged defect was not known or not reasonably scientifically knowable at the time the product was distributed.

**Sixty-fifth Defense**

65. Plaintiffs' claims are barred by their failure to comply with conditions precedent to the right to recover.

**Sixty-sixth Defense**

66. Plaintiffs' claims are barred in whole or in part by the doctrine of informed consent. Plaintiffs and Decedent were informed of the risks associated with treatment and willingly consented to treatment despite those risks. Specifically, Plaintiffs and Decedent gave informed consent to the prescribing physicians before taking Celebrex®, alone or in combination with any other drug(s).

**Sixty-seventh Defense**

67. The duty to obtain Plaintiffs' and Decedent's informed consent prior to prescribing Celebrex® alone or in combination with any other drug(s) rested solely with the prescribing physicians.

**Sixty-eighth Defense**

68. Plaintiffs may not assert a claim against Defendants for negligent misrepresentation as Plaintiffs and Decedent did not suffer a pecuniary loss as a result of any alleged misrepresentation by Defendants.

**Sixty-ninth Defense**

69. Plaintiffs' claims of negligent misrepresentation are barred by the failure to justifiably rely on any alleged misrepresentation of Defendants.

**Seventieth Defense**

70. Plaintiffs' claims of misrepresentation are barred because any alleged misrepresentation on which Plaintiffs or Decedent relied did not constitute a misrepresentation of material facts.

**Seventy-first Defense**

71. Plaintiffs' claims for breach of warranty are barred in whole or in part by the Defendants' disclaimers.

**Seventy-second Defense**

72. Plaintiffs' claims for breach of warranty are barred in whole or in part because they are not in privity with Defendants.

**Seventy-third Defense**

73. Defendants assert the defenses of expiration, limitation, and exclusion to any applicable express or implied warranty, if any be proved.

**Seventy-fourth Defense**

74. Plaintiffs' claims are barred in whole or in part because any warranties, if made, are excluded through course of dealing, course of performance and/or usage of trade.

**Seventy-fifth Defense**

75. Plaintiffs have failed to allege conduct warranting imposition of punitive damages under

1 Texas law.

2 **Seventy-sixth Defense**

3 76. The standards in Texas governing the award and review of damages for non-pecuniary  
4 damages, including damages for mental anguish and pain and suffering, are impermissibly  
5 vague or simply non-existent, and are inadequate to ensure that such awards do not include  
6 amounts intended as exemplary damages, which are impermissible in a compensatory damages  
7 award.

8 **Seventy-seventh Defense**

9 77. Plaintiffs' claims for punitive or exemplary damages are subject to the limitations and  
10 requirements of Chapter 41 of the Texas Civil Practice and Remedies Code, including the cap  
11 on exemplary damages set out in § 41.008(b).

12 **Seventy-eighth Defense**

13 78. Defendants plead the applicability of the Washington Products Liability Act, RCW 7.72  
14 et seq., and specially aver that Plaintiffs' common law claims are preempted by the statute and  
15 must be dismissed.

16 **Seventy-ninth Defense**

17 79. Plaintiffs' claim for non-economic damages is subject to the statutory limitations set  
18 forth in ORS 31.710.

19 **Eightieth Defense**

20 80. Plaintiffs are not entitled to a private right of action under ORS 646.638.

21 **Eighty-first Defense**

22 81. Defendants' conduct complied with the orders or rules of, or a statute administered by a  
23 federal, state or local government agency, and, accordingly, Defendants are not liable under  
24 ORS 646.608.

25 **Eighty-second Defense**

26 82. Defendants are entitled to an award of attorney fees pursuant to ORS 646.638(3).

27 **Eighty-third Defense**

28 83. Defendants avail themselves of all of the provisions, defenses, and standards of proof in

O.C.G.A. § 51-12-5.1 concerning punitive damages.

**Eighty-fourth Defense**

84. Plaintiffs' claims for strict liability are barred as to Defendants inasmuch as they are not a manufacturer of the drug Celebrex® within the meaning of O.C.G.A. § 51-1-11(b)(1) and applicable Georgia law.

**Eighty-fifth Defense**

85. Plaintiffs' claims for fraud and misrepresentation(s) are barred and should be dismissed because they have not been pled with sufficient particularity to meet the requirements of O.C.G.A. § 9-11-9(b).

**Eighty-sixth Defense**

86. Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

**Eighty-seventh Defense**

87. The claims asserted in the Complaint are barred, in whole or in part, because Defendants did not violate the Illinois Consumer Fraud and Deceptive Business Practice Act, 815 ILCS 505/1 *et seq.*, and/or this Act is not applicable to this matter and/or to Plaintiffs and Decedent.

**Eighty-eighth Defense**

88. Plaintiffs' claims for punitive damages are barred, in whole or in part, by § 2315.21 of the Ohio Revised Code and are subject to all provisions of the Ohio Revised Code.

**Eighty-ninth Defense**

89. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources and the provisions of the Ohio Revised Code.

**Ninetieth Defense**

90. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Ohio law.

**Ninety-first Defense**

91. Plaintiffs' damages, if any, must be reduced by the percentage of fault attributable to Plaintiffs and to nonparties as provided by the Ohio Revised Code.

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**Ninety-second Defense**

92. One or more of Plaintiffs' claims for damages are subject to statutory limits on certain types of damages, and the Court is without jurisdiction to enter judgment for Plaintiffs beyond the limits set forth in the Ohio Revised Code.

**Ninety-third Defense**

93. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiffs' claims, including the limits and restrictions on damages set forth herein.

**Ninety-fourth Defense**

94. Any injuries and damages suffered by Plaintiffs and Decedent, which injuries and damages are expressly denied, are the direct and proximate result of Plaintiffs' and Decedent's own comparative and contributory negligence and Plaintiffs' recovery should be barred, or alternatively, reduced proportionately to Plaintiffs' and Decedent's own comparative negligence.

**Ninety-fifth Defense**

95. Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required by Pa. R. Civ. P. 1019(b).

**Ninety-sixth Defense**

96. Defendants assert all affirmative defenses applicable under the Louisiana Products Liability Act, La. Rev. State. § 9:2800.51, et seq.

**Ninety-seventh Defense**

97. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

**PRAYER**

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;

- 1 3. That Defendants be awarded their costs for this lawsuit;
- 2 4. That the trier of fact determine what percentage of the combined fault or other liability
- 3 of all persons whose fault or other liability proximately caused Plaintiffs' and
- 4 Decedent's alleged injuries, losses or damages is attributable to each person;
- 5 5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater
- 6 than an amount which equals their proportionate share, if any, of the total fault or other
- 7 liability which proximately caused Plaintiffs' and Decedent's injuries and damages; and
- 8 6. That Defendants have such other and further relief as the Court deems appropriate.

9  
10 October 8, 2007

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26 LLC  
27  
28

**JURY DEMAND**

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

October 8, 2007

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